



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.

09/806,370

Confirmation No. 8568

Applicant

: Randall K. Holmes et al

Filed

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TC/A.U.

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Examiner

: Virginia A. Portner

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Customer No.

: 38199

Mail Stop RCE
 Commissioner for Patents
 P. O. Box 1450
 Alexandria, VA 22313-1450

DECLARATION

Sir:

I, Mary E. Bak, residing at 1415 Comly Court, Maple Glen, PA, 19002, a citizen of the United States of America, do declare and state that:

1. I am one of the named attorneys of record in the above-identified patent application.
2. This Declaration is submitted in the above-identified application in response to the Examiner's rejection under 35 USC § 112, first paragraph in the Office Action dated March 10, 2004.

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3. Specifically, this Declaration is submitted to support the insertion by amendment of SEQ ID NO: 1 into the specification, which is the mature wild-type cholera holotoxin subunit A sequence as set forth in Domenighini *et al.*, International Patent Publication No. WO 93/13202 (hereinafter Domenighini) cited in the specification at page 38, line 10 and properly incorporated by reference. See, Exhibit A attached herewith.

4. The same sequence appears in Mekalanos *et al.*, 1983 *Nature*, 306:551-557 (hereinafter Mekalanos) cited in the specification at page 2, line 4 in the context of the entire CT sequence with subunit B and 5' and 3' untranslated regions. See, Exhibit B. The mature subunit A is indicated in Mekalanos by the first amino acid appearing under the first mature amino acid "N" in the sequence. SEQ ID NO: 1 is a duplicate of the mature subunit A sequence as set forth in both Domenighini and Mekalanos.

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: July 12, 2004 By: Mary E. Bak
Mary E. Bak